

## **REMARKS**

### **I. Amendments to the Claims**

Following entry of this amendment, claims 35-40, 44-52, and 57-59 are pending. Claims 1-34, 41-43, and 53-56 have been cancelled. Claims 35, 36, 58, and 59 are amended herein. Support for the amendment of claims 35, 36, 58 and 59 is found in the third paragraph on page 4 and the second paragraph of page 5 of the translated specification. In particular, support for the non-chaotropic character of the cations is found in the statements "based on the use of non-chaotropic buffer formulas" and "then the lysated sample is mixed with a non-chaotropic binding buffer according to this invention" that appear in the specification as filed.

None of the amended claims include new matter. Entry and allowance of all of the amended claims are hereby requested.

### **II. Specification Objections**

The Office Action objects to the disclosure as allegedly improper due to a typographical error. The suggested correction has been made, and this objection is now moot.

### **III. Claim Rejections - 35 U.S.C. § 112**

Claims 35-47, 49-52, 57 and 59 stand rejected under 35 U.S.C. § 112, second paragraph, for allegedly being indefinite. The claims have been amended to distinctly claim the subject matter which applicant regards as the invention, and this objection is now moot.

Claims 35-47, 49-52, 57 and 59 stand rejected under 35 U.S.C. § 112 second paragraph, for allegedly being incomplete for omitting essential elements. The amendments herein remedied the alleged omission, and this objection is now moot.

Claim 36 has been rejected due to alleged lack of proper antecedent basis. The amendments herein remedied the alleged improper antecedence, and this objection is now moot.

Additionally, the Office Action objects to the term "monovalent" for allegedly lacking clear redefinition. This language has been removed, and the rejection is now moot.

All of the rejections under 35 U.S.C. § 112, second paragraph have been addressed and overcome by amendment of claims. Withdrawal of these rejections and allowance of the claims are respectfully requested.

#### IV. Claim Rejections - 35 U.S.C. § 102

Claims 35-40, 44-47, 49, 50, 52, 58 and 59 stand rejected under 35 U.S.C. § 102(b) for alleged anticipation by US Patent 6,376,194 by Smith *et al.* ("Smith"). Applicants respectfully disagree. For the claims to be anticipated by Smith, it must include, either expressly or inherently, all of the limitations in the claims. *See Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Smith does not teach all of the limitations of the amended claims; therefore it does not anticipate the present invention.

Smith does not anticipate amended claims 35-40, 44-47, 49, 50, 52, 58 and 59, because it does not expressly or inherently disclose the limitation of utilizing non-chaotropic ions. Unlike the present invention, Smith is a combination of an ion exchange procedure and a chaotropic binding protocol. Embodiments of the present invention provide a usage of combinations of non-

chaotropic ions such as  $\text{NH}_4^+$ ,  $\text{Mg}^{2+}$ ,  $\text{Ca}^{2+}$ ,  $\text{Zn}^{2+}$  or  $\text{Mn}^{2+}$ , which efficiently reduce salt concentrations for nucleic acid binding. This allows the extraction procedure to be performed at low salt concentrations and without the washing steps necessary for the extraction method reported in Smith.

As Smith does not explicitly or inherently disclose the limitation of using non-chaotropic ions, withdrawal of this rejection and allowance of the claims are respectfully requested.

V. Claim Rejections - 35 U.S.C. § 103

Claims 51 and 57 stand rejected under U.S.C. § 103(a) for allegedly being unpatentable over Smith in view of European Patent 0580305 by Seed *et al.* ("Seed"). The claims, as amended, are not anticipated by this combination of references, because the references fail to teach or suggest all of the limitations of the claims separately, or in combination. In addition, there is no motivation present to combine these references.

To establish a *prima facie* case of obviousness one must analyze the four factors provided by the U.S. Supreme Court in *Graham v. John Deere*, 383 U.S. 1, 17-148 (1966). The four factors are: (a) determining the scope and contents of the prior art; (b) ascertaining the differences between the prior art and the claims of the present invention; (c) resolving the level of ordinary skill in the pertinent art; and (d) evaluating evidence of secondary indicia of non-obviousness such as meeting a long felt need, succeeding where others have failed, or demonstrating success in the market. Because the prior art does not include the limitations in the claims as amended, it is insufficient to establish a *prima facie* case of obviousness.

The scope and contents of the prior art do not support an obviousness rejection of the claims as amended. Neither Smith nor Seed teaches the limitation of the present invention involving the usage of combinations of non-chaotropic ions such as  $\text{NH}_4^+$ ,  $\text{Mg}^{2+}$ ,  $\text{Ca}^{2+}$ ,  $\text{Zn}^{2+}$  or  $\text{Mn}^{2+}$ . This limitation allows for the extraction procedure in the present invention to be performed at low salt concentrations without the washing steps.

In addition to the references not possessing the limitations detailed in the amended claims separately or in combination, there is no motivation for one skilled in the art to combine these references. The procedure from Seed is based on an ion exchange method to bind nucleic acids independent of the pH and salt concentration in solutions. One skilled in the art would know that the raw silica material used in the present invention would never work with the method disclosed in Seed. It is more likely that one skilled in the art would consider using a solid phase material with organic modifications such as a hydroxyl group. Additionally, one skilled in the art is unlikely to look to this reference because to extract nucleic acids they would likely use bivalent ions to avoid chelators in the elute. This is in contrast to the system disclosed in the present invention for which a chelator, such as EDTA or EGTA, is needed to elute the nucleic acids completely.

The system disclosed in Smith is a combination of an ion exchange procedure, related to the method in Seed, and a chaotropic binding protocol such as the one found in Boom et al. The combination of chaotropic methods of binding DNA to pure silica and the method of binding DNA by ion exchange systems would not be expected to lead to the results of the present invention, and therefore no motivation exists to combine these references.

The present invention needs two different kinds of binding nucleic acids, two different kinds of binding materials and two different buffer systems. One skilled in the art may try the

procedure with more than one binding material, or with a binding material with two characteristics on one surface. However, it is unlikely based on the cited references that one skilled in the art would know to use pure silica, based solely on the fact that it is one of the described surfaces in the so called "Mixed-bed solid phase" disclosed in Smith.

Furthermore, one skilled in the art would likely attempt to divide these methods into single features, although this would be a step backward, because it would involve the use of a chaotropic binding system in a high salt concentrations with Silica, or as disclosed in Seed, an ion exchange protocol system where silica is not useable at all. This would be contradictory to the present invention that involves a non-chaotropic binding system in a low salt concentration where Silica is one of many materials that may be used.

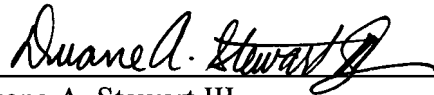
As discussed above, neither Smith, nor Seed includes all of the limitations of the amended claims, either alone or in combination and no motivation exists to combine these references. The rejections should be withdrawn, and the claims should be reconsidered and allowed.

**CONCLUSION**

Applicants believe that the amendments and remarks set forth in this paper place this Application in a condition for allowance, and such action is respectfully requested at an early date. If the Examiner believes that personal communication will expedite the prosecution of this Application, the Examiner is invited to telephone the Applicants' undersigned attorney directly.

Respectfully submitted,

Dated: October 17, 2007



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